Ionizing Radiation - Mammography ORR #2011-010 LR

The following is a review of public hearing testimony pertaining to the proposed changes to the mammography rules. The hearing was held on September 5, 2012.

Organization	Patricia Miller, M.D. and Ralph Lieto, M.S.E. Michigan Radiological Society
Comment and Response	Comment: The Michigan Radiological Society supports the work of the Michigan Department of Licensing and Regulatory Affairs to update its mammography rules and make them consistent with the Mammography Quality Standards Act (MQSA). This will significantly improve the relevancy of the regulations.
	Comment: The American College of Radiology (ACR) is currently revising its standards for stereotactic breast biopsy accreditation. The department should delay adopting the ACR's stereotactic breast biopsy requirements until the new standards are finalized. Response: The department feels it should continue with the rule promulgation process regardless of the current status of the new ACR standards. The rules can be amended to adopt the new ACR standard at such time as it is finalized. The department has noted that the current versions of the ACR's "Mammography Accreditation Program Requirements" and "Stereotactic Breast Biopsy Accreditation Program Requirements" have been updated. The department intends to reference the May 2012 versions of both in the rules.
	Comment: Rule 607(1) – The commenter would like clarification of the difference between "location" and "address". Further, the commenter wonders whether a new application must be submitted if a machine is moved to a new "location" within a previously approved "address." Response: The department agrees that the language is vague. The language will be changed as follows: "If mammography is performed at more than 1 ~~location or~~ address, a separate application shall be used for each ~~location or~~ address."
	Comment: Rule 607(1)(b) – The commenter would like clarification of the phrase "any individual who actually performs mammography". Response: The language will be changed as follows: "any ~~individual~~ **radiologic technologist** who ~~actually~~ performs mammography"

	Comment: Rule 607(1)(d)(iii) – The requirement for laser printer information in the application should be removed unless images printed from the laser printer are used for clinical diagnosis. Response: Currently, the Mammography Quality Standards Act (MQSA) requires that all facilities performing screening or diagnostic imaging have the ability to provide hard copy images of clinical quality to patients or their representatives. In the case of stereotactic breast biopsy, facilities may not produce hardcopy images. The application requests basic information relevant to hardcopy images. The department will change the language as follows: "**Laser printer information, as applicable, for machines using digital imaging.**"
	Comment: Rules 610 and 611 - The commenter objects to the department's alternative authorization process and to the potential use of unaccredited machines. The commenter asks what criteria would be used to "contract with mammography experts." Response: The department does not have the statutory authority to require mammography facilities to become accredited by an independent body. The alternative authorization process is intended to make the quality standards for unaccredited facilities equivalent to those accredited by the ACR. The MQSA makes the alternative authorization clause irrelevant for diagnostic and screening mammography in Michigan since it requires these facilities to be accredited by the ACR. For stereotactic breast biopsy, there is no accreditation requirement. One of the major goals of this rule revision was make the standards for stereotactic breast biopsy in Michigan more closely aligned with those of the ACR. The department intends to use the ACR as the standard and plans to contract with the ACR for image evaluation. The department intends to remove the requirement of 610(e)(iii) that digital images submitted for authorization be hardcopy. The department anticipates that the ACR will soon eliminate this requirement in their accreditation process.
	Comment: Rule 610(1)(b) – The commenter requests that the requirement to provide laser printer quality control data be revised to "laser printer information, if images generated by laser printer are used for clinical diagnosis." Response: Currently, the MQSA requires that all facilities performing screening or diagnostic imaging have the ability to provide hard copy images of clinical quality to patients or their representatives. In the case of stereotactic breast biopsy, facilities may not produce hardcopy images. The ACR accreditation program for stereotactic breast biopsy requires the quality control program include an evaluation of the hardcopy output quality at least monthly if hardcopies are produced from digital data. This subdivision states that the applicant shall provide "processor or laser film printer quality control data and corrective actions, *if any* [emphasis added], taken as a result of that data for a 30-day period beginning after the date the application was sent to the department." If the machine in question is a stereotactic unit for which no hardcopy quality control data are required, then there will be no quality control data to provide. The department intends to leave the language unchanged.

	Comment: Rule 610(1)(d) – Thermoluminescent dosimeters are not standard or practical for determinations of the data requested in this subdivision. Response: This refers to obtaining a mean glandular dose for accreditation purposes. The ACR provides a dosimeter card in its application packet. The "department-approved" device would be substantially the same. The department will revise the language as follows: "~~For each machine, determinations~~ **Determinations** of the half-value layer, radiation exposure at skin entrance, and mean glandular dose that are made with the use of a department-approved ~~thermoluminescent~~ dosimetry device"
	Comment: Rule 627(b)(i) – This requirement should be changed to remove board certification in "radiology" from the list of eligibility requirements for interpreting physicians. The commenter notes that the certifying boards have not certified in "radiology" since the late 1980s and currently certify in "diagnostic radiology." Response: The commenter's point is well taken and reference to board certification occurs in 627(b)(i) and 627(b)(ii). Although it is true that the boards no longer certify in "radiology", there are physicians working in the state who meet their initial qualifications on the basis that they are board certified in "radiology." The same language is contained in the statute. The department plans to leave the language unchanged.
	Comment: Rule 627(d) – The commenter requests clarification on the meaning of the word "subdivision" in the last sentence and suggests replacing "subdivision" with "rule". Response: According to the style established for writing administrative rules in Michigan, a subdivision of a rule is a statement dependent upon and anticipated by preceding material. It is preceded by a colon. 627(d) is a subdivision.
	Comment: Rule 655(2) – The commenter suggests that the wording be changed for clarity. Response: The department agrees that the wording of this subrule is awkward. The same language occurs in subrule 677(2) for stereotactic units. The language will be changed in both subrules as follows: "the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum **tube** potential is ~~limited electrically or mechanically to~~ less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum **tube** potential is ~~more than~~ **greater than** 35 kilovolts."

	Comment: Rule 655(3) – The phrase "portable shielding" should be changed to "shielding" for simplicity. Response: The department agrees. Changing the phrase will not cause any changes to the meaning or intent of the wording. The new subrule will read: "**An individual operating a mobile or portable mammography machine shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless shielding is provided as specified in subrule (2) of this rule.**"
	Comment: Rule 655(5) – The commenter requests justification for placing restrictions on the use of mobile or portable accredited mammographic equipment by hospitals or physicians' offices. Response: In the context of the Ionizing Radiation Rules, a "mobile" x-ray machine is a machine on wheels that can be moved from room to room within a building. We are not referring to x-ray machines that have been installed in a vehicle which patients enter to have their examination. We classify machines in a vehicle as "transportable" machines and these are considered to be fixed for the purposes of radiation protection. Mobile equipment may not produce images with the same high quality that fixed equipment can produce. Therefore, their use is limited to patients who cannot be moved to a fixed installation. This subrule is analogous to subrule 353(3) in Part 7 - Medical X-ray Installations.
	Comment: The department needs to set qualification requirements for "stereotactic breast biopsy physicians" equivalent to those of the ACR. Response: At this time the department does not have the statutory authority to promulgate rules setting requirements for "stereotactic breast biopsy physicians." When the public health code mammography amendments setting qualifications for interpreting physicians were passed in 1994, the ACR did not have accreditation standards for stereotactic breast biopsy. According to legal staff of the Office of Regulatory Reinvention: "The statutory requirements included in 13523(g) are specific to physicians interpreting diagnostic mammography, and in no way does the statute give the department authority to write rules to set requirements for physicians who interpret images for stereotactic breast biopsy."
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	Comment: Rule 679 – Subdivisions (g) through (o) should be deleted since they would interfere with the practice of medicine and would potentially compromise the patient physician relationship. Also, nothing in the rule describes "terminology" as stated in its title. Response: All the items listed in rule 679 were taken directly from the image labeling and physician's report sections of the "ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures." The department is willing to defer to the facility's judgment rather than impose these report requirements in rule. The department believes that the recommendations of the ACR represent the current best practice in the field. The department will change the draft rule as follows: "**R 325.5679 Report contents.** **Rule 679. A stereotactic breast biopsy facility shall prepare a written report of the results of each stereotactic breast biopsy procedure. The stereotactic breast biopsy report shall include all of the following information:** **(a) The name of the patient and an additional unique patient identifier.** **(b) The date of the procedure.** **(c) The name of the stereotactic breast biopsy physician who conducted the procedure.** **(d) The procedure performed.** **(e) Designation of the left or right breast.** **(f) Description and location of the lesion.**"
	Comment: Rule 680 – This rule should be deleted since all stereotactic breast biopsy procedures require the referral of a health care provider. The rule is a misapplication of a screening mammography requirement to stereotactic breast biopsy. Response: The department agrees and will delete this rule from the draft rule set.

	Comment: Rule 682(1)(a) – The subdivision is confusing and needs clarification to be consistent with rule 657 for regular mammography. Response: The department believes the language of the rule is virtually identical to the language in rule 657. The "ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedure" recommends that image retention times "be consistent with the facility's policies for retention of mammograms and in compliance with federal and state regulations." The MQSA requires that images and reports be kept for "not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility." In Michigan, the Public Health Code (MCL 333.20175) specifies medical record retention of not less than 7 years, both rules 657 and 682(1)(a) are modified versions of the language of the MQSA, where 5 years is replaced by 7 years as the minimum retention time.
	Comment: Rule 683 – Subdivisions (d) through (f) should not be required since some machines currently in use are not capable of providing this information. The commenter recommends changing "shall" to "should" for these image labeling elements. Response: The department agrees. Those requirements will be removed and the remaining subdivisions relabeled accordingly. The new draft rule will read as follows: "**R 325.5683 Stereotactic breast biopsy image identification.** **Rule 683. A stereotactic breast biopsy image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:** **(a) Name of patient and an additional unique patient identifier.** **(b) Date of the procedure.** **(c) Designation of left or right breast.** **(d) Cassette identification, if applicable.** **(e) Stereotactic breast biopsy unit identification if there is more than 1 unit in the facility.**"
	Comment: Rule 685 – The language in subdivision (d) is "inconsistent" and needs clarification. The commenter goes on to say that it appears the meaning of the subdivision is to allow for the delegation of quality control tests. Response: The language of this rule is consistent with the language used by the MQSA in assigning quality assurance tasks to a quality control technologist. Under the MQSA regulations, quality control tasks may be delegated to qualified individuals as long as the lead quality control technologist reviews the work performed by other staff to ensure compliance with the quality control testing requirements. For clarity, the department will change the sentence as follows: "**The tasks are to be performed by the quality control technologist, but may be delegated to other qualified personnel by the quality control technologist.**"

	Comment: Rule 687(e) – This requirement is appropriate for film-screen but not for digital systems. The commenter questions the origin of a 20% upper bound for repeats and asks whether repositioning should be counted as a repeat since repositioning is fairly common when performing stereotactic breast biopsy. The commenter also notes this subdivision sets no upper bound for facilities performing fewer than 150 cases in a six month period. Response: The department believes that repeat analysis is an appropriate quality assurance indicator for both film-screen and digital systems. The ACR offers a sample worksheet for repeat analysis in stereotactic breast biopsy facilities using digital imaging. Among the items included in the analysis are positioning, patient motion, image exposure problems, and equipment failures. The 20% limit is taken from the ACR's Stereotactic Breast Biopsy Quality Control Manual. The department believes that facilities should perform a repeat analysis regardless of case volumes. For statistical reasons, 150 cases is thought to be a good minimum for setting a meaningful limit on repeats. For facilities performing fewer cases, the department believes that repeat analysis will still provide useful information that can be used to maintain quality. We agree that the rule should be clarified. The new draft language is: "**A repeat analysis shall be performed at least semiannually. If the overall repeat or reject rate exceeds 20% based on an image volume of not less than 150 patients, the reason for the change shall be determined. A repeat analysis shall be assessed semiannually even if fewer than 150 patients are examined during that period.**"
	Comment: Rule 695 – The department should specify that this rule only applies to facilities using screen-film imaging. The department should consider moving this rule to 687(f). Response: The department will leave this rule at its current location but will clarify that it applies to screen-film only. The new rule title will be: "**R 325.5695 Cleanliness in facilities using screen-film systems.**"
	Comment: Rule 697 – The word "system" is confusing in the context of infection control. The commenter recommends modifying the language for clarity. The commenter questions the department's statutory authority and expertise to perform infection control inspections. Response: The department will change the draft rule as follows: **"R 325.5697 Infection control.** **Rule 697. A stereotactic breast biopsy facility shall establish and comply with procedures to be followed for cleaning and disinfecting stereotactic breast biopsy equipment after contact with blood or other potentially infectious materials. The procedures shall include methods for documenting facility compliance with the infection control procedures**"

	Comment: The commenter states that the department has underestimated the cost to comply with the addition of rules specific to stereotactic breast biopsy. The commenter states that annual machine testing and continuing education costs are not factored into the department's analysis. Response: The current Part 14 already requires stereotactic breast biopsy machines to be evaluated by a qualified "radiation physicist". Physicists are performing most, if not all, of the machine tests specified by the ACR accreditation program. We believe that many radiologic technologists and medical physicists are already meeting the continuing education requirements. The requirements specific to stereotactic breast biopsy in the draft rules can be used as part of other continuing education requirements already in place. Radiologic technologists working in stereotactic breast biopsy are required by the registering body (ARRT) to obtain 24 credits of continuing education every two years. The draft rule simply states that some of these credits (i.e. more than one) be "pertinent to stereotactic breast biopsy." For medical physicists, the continuing education requirement for medical physicists of 3 credits per 36 months would count toward the 15 credits they are required to obtain pursuant to the MQSA. There is no net increase in the number of continuing education credits required.
Organization	Don Parry, C.H.P. Michigan Department of Licensing and Regulatory Affairs, Radiation Safety Section
Comment and Response	Comment: Rule 605(a) – As currently written it appears that a mammography machine that has a stereotactic add-on may only need to meet the ACR's Mammography Accreditation Program and not the Stereotactic Breast Biopsy Accreditation Program since 605(a) says that the radiation machine can meet ANY of the following. Response: The department agrees. Draft rule 605(a)(ii) is changed to the following: "**A machine used for stereotactic breast biopsy and the facility in which the machine is used meet the criteria of the American college of radiology stereotactic breast biopsy accreditation program dated May 2012, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only. A mammography machine that uses a specially designed add-on device for breast biopsy shall be authorized for both mammography and stereotactic breast biopsy.**"
	Comment: Rule 634 - Since we will no longer approve mammography physicists, what happens to those currently approved that do not meet the MQSA requirements in 21 C.F.R. 900.12(a)(3), such as not being board certified? Once the new rule passes are there no longer any Michigan approved mammography physicists, or do they remain approved until their certificate expires? It would be nice to somehow grandfather these in these existing physicists. Response: At the time of promulgation, the department will issue non-expiring certificates tor physicists who were qualified prior to the effective date of the new rules which will effectively grandfather those physicists. After the effective date of the new rules, a physicist would need to demonstrate that they meet the qualifications requirements of the MQSA.

	Comment: Rules 637, 657, 658, 667, and 668 – These rules reference 900.12(b), but it is unclear if this includes the various alternative standards approved by FDA for the various parts of 900.12. It would be nice to include these, and possibly future alternative standards in our rules to maintain consistency with FDA. Response: As written, the draft rules do not incorporate the alternative standards of 21 C.F.R. 900.18. The department agrees and will add the following rule: "**R 325.5669 Alternative requirements for personnel, x-ray equipment, medical records and mammography reports, and quality assurance.** **Rule 669. The department may accept alternatives to a quality standard under 21 CFR 900.12 that have been approved by the U.S. Food and Drug Administration under 21 CFR 900.18, "Alternative requirements for § 900.12 quality standards" (2000).**"
	Comment: Rule 688(f)(ii) – Some units (Fischer and now Siemens units) do not have the ability to measure the signal level for an ROI. The ACR stereotactic QC manual gives another test for those units. Response: The department will add, 688(f)(iii): "**For digital systems that are not equipped with region of interest signal measurements, the machine will meet the receptor uniformity requirements specified by the manufacturer.**"